UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,581	02/05/2004	Richard S. Ginn	704117.4011	6733

34313 7590 04/29/2008

ORRICK, HERRINGTON & SUTCLIFFE, LLP
IP PROSECUTION DEPARTMENT
4 PARK PLAZA
SUITE 1600
IRVINE, CA 92614-2558

EXAMINER	
WOODALL, NICHOLAS W	

ART UNIT	PAPER NUMBER
3733	

MAIL DATE	DELIVERY MODE
04/29/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/773,581	GINN, RICHARD S.	
	Examiner	Art Unit	
	Nicholas Woodall	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,10-13 and 21-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,10-13 and 21-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to applicant's amendment received on 01/16/2008.

Response to Amendment

2. The affidavit under 37 CFR 1.132 filed 01/16/2008 is insufficient to overcome the rejection of claims1-8, 10-13, and 21-27 based upon 35 U.S.C. 103(a) as set forth in the last Office action because: the applicant's argument that the disclosure of Kuslich being relied upon by the examiner in the previous office action is not supported by the provisional application is not persuasive. On page 8 lines 14-18 of the provisional application supplied by the applicant, Kuslich discloses at least one embodiment as follows, "...the invention consists of ***any continuous band or ring that would be placed around and near the outer margins of the intervertebral disc. A suture or preferably a flattened, braided, or woven strand or cord, for instance, that was placed circumferentially about a disc and tied to make a tension-resisting ring, would qualify"*** (emphasis added by the examiner). Therefore, basic principals of the embodiment relied upon by the examiner are supported by the provisional, i.e. a flat woven band placed around the spinal disc and the ends tied together. The only limitation not supported by the provisional is the band being used for electrical stimulation of bone growth.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-8 and 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuslich (U.S. Publication 2002/0077701) in view of Weeden (U.S. Patent 4,606,335).

Kuslich discloses various embodiments of a device comprising a cerclage type embodiment, wherein the device comprises a band of biocompatible material having a height of at least that of a spinal disc to be treated, two ends, and a length sufficient enough to wrap around the exterior of a spinal disc (page 3 paragraph 057 of the publication and page 8 lines 14-22 of the provisional application). The first end of the band includes an opening capable of receiving a hook (claim 3). The band is a woven element, wherein the weave includes openings making the element porous. The openings of the weave are capable of receiving a hook element. The height of the band is capable of covering a spinal disc and at least a portion of at least one vertebra adjacent the spinal disc. The device further comprises a heal-promoting material and an extra-cellular matrix material, such as hydroxyapatite, on at least one side of the band (page 13 lines 6-10 of the provisional application). The device comprises a non-porous material or porous material depending on the intended use of the device (page 13 lines 1-6). The device comprises a second end that includes a connector capable of connecting the second end of the device to another portion of the device. Kuslich discloses the device is placed circumferentially placed about the disc and tied together. The second end of the device is capable of being tied to another portion of the device

and requires at least one thread extending from the second end of the device. The second end of the device does not need to be interpreted as the extreme tip of the device, the end can include an end portion wherein a portion of the second end comprises band includes the extreme portion tied to the other end of the device. Kuslich fails to disclose further comprising an elongate member comprising a handle on the proximal end and a connector element on the distal end. Wedeen teaches a device comprising an elongated member comprising a handle on the proximal end and a connector element on the distal end, wherein the connector is a hook in order to position a cerclage device around a bone (column 1 lines 5-7). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Kuslich with an elongated member comprising a handle on the proximal end and a connector element on the distal end in view of Weeden in order to position a cerclage device around a bone.

The combination of Kuslich and Weeden disclose a device wherein the elongate member is capable of pulling the band around the exterior of the spinal disc. It is noted that when the surgeon decides to position the cerclage device the connector element of the elongate member is connected to an end of the cerclage device, wherein that end is then releasably connected to the connector element of the elongate member and is therefore interpreted as the first end of the band.

5. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuslich (U.S. Publication 2002/0077701) in view of Weeden (U.S. Patent 4,606,335) further in view of Michelson (U.S. Patent 6,120,502).

The combination of Kuslich and Weeden disclose the invention as claimed except for a portion of the implant being electrically conductive and the device comprising a source of electrical energy coupled to the conductive portion of the device. Michelson discloses an implant including a body having an electrically conductive portion and further comprising a source of electrical energy coupled to the conductive portion of the implant in order to electrically stimulate bone growth to increase the rate of osteogenesis (column 2 lines 4-45). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Kuslich as modified by Weeden wherein the implant includes an electrically conductive portion and the device further comprises an electrical energy source coupled to the conductive portion in view of Michelson in order to electrically stimulate bone growth to increase the rate of osteogenesis.

6. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuslich (U.S. Publication 2002/0077701) in view of Weeden (U.S. Patent 4,606,335) and Mikhail (U.S. Patent 5,308,349).

Kuslich discloses various embodiments of a device comprising a cerclage type embodiment, wherein the device comprises a band of biocompatible material having a height of at least that of a spinal disc to be treated, two ends, and a length sufficient enough to wrap around the exterior of a spinal disc (page 3 paragraph 057 of the publication and page 8 lines 14-22 of the provisional application). The first end of the band includes an opening capable of receiving a hook (claim 3). The band is a woven element, wherein the weave includes openings making the element porous. The

openings of the weave are capable of receiving a hook element. The height of the band is capable of covering a spinal disc and at least a portion of at least one vertebra adjacent the spinal disc. The device further comprises a heal-promoting material and an extra-cellular matrix material, such as hydroxyapatite, on at least one side of the band (page 13 lines 6-10 of the provisional application). The device comprises a non-porous material or porous material depending on the intended use of the device (page 13 lines 1-6). The device comprises a second end that includes a connector capable of connecting the second end of the device to another portion of the device. Kuslich discloses the device is placed circumferentially placed about the disc and tied together. The second end of the device is capable of being tied to another portion of the device and requires at least one thread extending from the second end of the device. The second end of the device does not need to be interpreted as the extreme tip of the device, the end can include an end portion wherein a portion of the second end comprises band includes the extreme portion tied to the other end of the device. Kuslich discloses the invention as claimed except for the device further comprising an elongate member comprising a handle on the proximal end and a connector element on the distal end and a fork member. Weeden teaches a device comprising an elongated member comprising a handle on the proximal end and a connector element on the distal end, wherein the connector is a hook in order to position a cerclage device around a bone (column 1 lines 5-7). Mikhail teaches a device comprising a fork member comprising a proximal end and a distal end defining an axis in between (see Figures 8 and 9), wherein the distal end comprises a pair of tines comprising a transverse portion

extending generally parallel to one another transversely with respect to the axis in order to distract adjacent bones of a joint. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Kuslich with an elongated member comprising a handle on the proximal end and a connector element on the distal end in view of Weeden and a fork member in view of Mikhail in order to position a cerclage device around a bone and to distract adjacent bones of a joint.

The combination of Kuslich as modified by Weeden further modified by Mikhail discloses a device wherein the elongate member is capable of pulling the band around the exterior of the spinal disc. It is noted that when the surgeon decides to position the cerclage device the connector element of the elongate member is connected to an end of the cerclage device, wherein that end is then releasably connected to the connector element of the elongate member and is therefore interpreted as the first end of the band.

The combination of Kuslich as modified by Weeden further modified by Mikhail disclose a device wherein the transverse portions of each tine comprises a tip and a heel disposed proximal to the tip, a length between the tip and the heel wherein the tip is capable of engaging a first vertebra and pivotally engaging a second vertebra with the heel to adjust a distance between the vertebrae. Mikhail teaches a device for distracting joints as discussed above comprising the structure required by the claims that is fully capable of being used on a joint between two vertebrae of the spine.

7. Claims 1-8, 10, 11 and 23-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuslich (U.S. Publication 2002/0077701) in view of Kaladelfos (U.S. Patent 6,494,887).

Kuslich discloses various embodiments of a device wherein the device comprises a band of biocompatible material having a height of at least that of a spinal disc to be treated and a first end and a length sufficient enough to wrap around the exterior of a spinal disc. The first end of the band element includes an opening capable of receiving a hook. The device further comprises a heal-promoting material and an extra-cellular matrix material, such as hydroxyapatite, on at least one side of the band (page 13 lines 6-10 of the provisional application). The device comprises a non-porous material or porous material depending on the intended use of the device (page 13 lines 1-6). The device comprises a second end that includes a connector capable of connecting the second end of the device to another portion of the device. Kuslich discloses the device is placed circumferentially placed about the disc and tied together. The second end of the device is capable of being tied to another portion of the device and requires at least one thread extending from the second end of the device. The second end of the device does not need to be interpreted as the extreme tip of the device, the end can include an end portion wherein a portion of the second end comprises band includes the extreme portion tied to the other end of the device. Kuslich discloses the invention as claimed except for the device further comprising an elongate member, wherein the elongate member includes a proximal end including a handle and a curved distal end including a connector, such as a hook, and a guide member,

wherein the guide member includes a proximal end and a curved distal end having a radius of curvature substantially similar to an exterior perimeter of a spinal disc and a lumen extending between the proximal and distal ends capable of allowing at least a portion of an elongate element to pass. Kaladelfos teaches a device comprising an elongate member (50), wherein the elongate member includes a proximal end including a handle and a curved distal end including a connector, such as a hook (54), and a guide member (12), wherein the guide member includes a proximal end including a handle and a curved distal end having a radius of curvature substantially similar to an exterior perimeter of a spinal disc and a lumen extending between the proximal and distal ends capable of allowing at least a portion of the elongate element to pass in order to insert an elongated element, such as a cerclage device, into a patient (column 1 lines 63-65). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Kuslich further comprising an elongate member and a guide member in view of Kaladelfos in order to insert an elongate element, such as a cerclage device, into a patient.

The combination of Kuslich as modified by Kaladelfos discloses a device wherein the elongate member is capable of pulling the band around the exterior space of a spinal disc. The lumen comprises a slot having a height greater than a width of the elongate element and the height of the lumen extends substantially perpendicular to the radius of curvature of the distal end. The proximal end of the guide member defines an axis, wherein the distal end of the guide member terminates in a distal tip extending

transversely with respect to the axis. The height of the lumen extends substantially perpendicular to the radius of curvature of the distal end.

The combination of Kuslich as modified by Kaladelfos discloses the invention as claimed except for the device further comprising a pair of guide members. It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the combination of Kuslich and Kaladelfos including a pair of guide members, since it has been held that a mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Response to Arguments

8. Applicant's arguments filed 01/16/2008 have been fully considered but they are not persuasive. The applicant's argument that Kuslich is not proper prior art is not persuasive. As discussed above, the provisional discloses an embodiment comprising the generic elements of a woven or braided flat band placed circumferentially around a spinal disc and tied to make a tension-resisting ring. The applicant's argument regarding claim 1 being a Jepson style claim making the preamble a structural limitation is not persuasive. A Jepson style claim is used to admit that the structure of the preamble of a claim is known prior art and that the novelty of the invention is an improvement described in the body of the claim. To reject a Jepson claim the examiner is then required to find the structure of the preamble as well as the improvement in use with the admitted prior art. The examiner would like to note that the only structural limitation in the preamble of claim 1 is "an apparatus", which can be interpreted as any structure.

Furthermore, the Kuslich reference meets the functional limitations of the preamble wherein the device is used around the exterior of a spinal disc. The applicant's argument that Kuslich and Wedeen are not analogous art is not persuasive. The examiner would like to note, the examiner must determine what is "analogous prior art" for the purpose of analyzing the obviousness of the subject matter at issue. "Under correct analysis, any need or problem known in the field of endeavor at the time of the invention and addressed by the patent [or application at issue] can provide a reason for combining the elements in the manner claimed." KSR International Co. v. Teleflex Inc., 550 U.S. __, __, 82 USPQ2d 1385, 1397 (2007). Thus a reference in a field different from that of the applicant's endeavor may be reasonably pertinent if it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his or her invention as a whole (MPEP 2141.01(a) I). Wedeen teaches a device used to insert cerclage device around the outside of a bone (page 7 lines 19-20) and Kuslich discloses a cerclage device used on the outside of a spinal joint, i.e. around the outside of the vertebra bones. Therefore, the examiner believes that the references are analogous and the teachings of the references are capable of being combined as discussed above. The applicant's argument that Mikhail is not analogous art relative to the Kuslich and Weeden references is not persuasive. The examiner would like to reference MPEP 2141.01(a) I as discussed above. The combination of Kuslich and Weeden teach a device comprising a cerclage device used on the outside of a spinal joint and an insertion device for inserting cerclage devices around the outside of a bone and Mikhail discloses a teaches a device for distracting

two adjacent bones of a joint. Therefore, the examiner believes that the references are analogous art and the teachings of the references are capable of being combined as discussed above. The applicant's argument that Kuslich and Kaladelfos are not analogous art is not persuasive. First, the applicant's argument is based on using the interior embodiments of Kuslich, which is not proper as discussed above. Second, the applicant argues the examiner did not provide a motivation for combining the reference. The examiner provided the motivation on page 6 lines 7-8 of the previous office action. Third, the examiner would like to note that Kuslich teaches a cerclage device and Kaladelfos teaches an insertion device for a cerclage device. Therefore, the examiner believes that the references are analogous and the teachings of the reference are capable of being combined as discussed above. The applicant's argument that the opposite hand guides are not mere duplication of parts is not persuasive. The individual hand guides are individually referenced using reference numeral 150 in the application's drawings and are therefore disclosed as being duplicates of a similar part. The amendments to the independent claims changed the scope such that the references used must be capable of being used on the exterior of the spinal disc, which changes the scope of the claims, making this office action is **FINAL**.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for cited references the examiner felt were relevant to the application.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicholas Woodall whose telephone number is (571)272-5204. The examiner can normally be reached on Monday to Friday 8:00 to 5:30 EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas Woodall/
Examiner, Art Unit 3733
/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733